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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,462	02/23/2004	Humberto A. Berra	GLM-1042	8228
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MAYBACK & HOFFMAN, P.A. 5722 S. FLAMINGO ROAD #232 FORT LAUDERDALE, FL 33330				
EXAMINER				
PELLEGRINO, BRIAN E				
ART UNIT		PAPER NUMBER		
3738				
MAIL DATE		DELIVERY MODE		
03/17/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/784,462

Applicant(s)

BERRA ET AL.

Examiner

Brian E. Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-109 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-21, 24-29, 40-60, 65-67, 70-72, 75-77, 80-82, 85-87, 90-92 and 95-97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims withdrawn from consideration are 7-9,22,23,30-39,61-64,68,69,73,74,78,79,83,84,88,89,93,94 and 98-109.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/07 has been entered.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4,10,11,40,47,65-67 are rejected under 35 U.S.C. 102(b) as being anticipated by Quinn (6319278). Fig 5 shows a vascular repair device having a tubular graft body **61**, a structural framework having at least two stents **42,44**. Fig. 4 illustrates there can be a longitudinal support **48** that is curved in an S-shape and connected to the graft body. Thus, the support member when viewed in an orientation that the longitudinal axis and centerline of the support member are aligned it can be said that the support member is substantially

reverse-mirror symmetrical with respect to the longitudinal axis. It can also be construed that since the longitudinal support wraps or extends in a lateral direction, it has a partial helix shape. Quinn discloses the support is made of metal, such as stainless steel, col. 2, lines 30,31. Since the support is part of the framework, it is preformed in the curved shape. Additionally, since the ends of the support are welded, they form rounded end as seen in Fig. 2. The stent clearly has a linear profile and Quinn discloses the device having a circular cross-section, col. 2, lines 43-46. Regarding claim 47, the graft is fully capable of having a diameter of the vessel it is implanted in once the stent graft is expanded.

Claims 1-4,6,10,14,15,18,19,40,41,43,47,49,53,65-67,70-72,80-82 are rejected under 35 U.S.C. 102(b) as being anticipated by Philips et al. (WO 99/37242). Fig. 12 shows a stent graft having a graft body **S** and having multiple stents **F** connected to the graft body. It can also be seen there is a curved wire running the middle area to form a longitudinal support member, independent of the stents and along the sides also, page 28. This wire when viewed in an orientation that the longitudinal axis and centerline of the support member are aligned it can be said that the support member is substantially reverse-mirror symmetrical with respect to the longitudinal axis and the centerline. The longitudinal support wire is shorter than the entire support structural framework. It can also be construed that since the longitudinal support wraps or extends in a lateral direction, it has a partial helix shape. Philips et al. disclose the support wire is made of metal, such as nitinol, page 19, last paragraph. The wire support

is fully capable of being preformed into a curved shape. Regarding claim 18, since there are end stents **M** and the wire support member does not extend the entire distance between these end stents, the stent graft forms a gimbal at an end. Regarding claims 47,49,53, Philips discloses the graft body has a diameter at least as large as the diameter of the vessel in which it is implanted, page 27. Regarding claims 66,71,81, since the stent graft has a length, clearly the stents have linear longitudinal profiles. With respect to claims 67,72,82, Philips also discloses the graft body is tubular, thus the stents are circular, pages 14,27.

Claims 25-29,45,46,57,59,90-92,95-97 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Van Schie (2003/88305). VanSchie shows a stent graft having a plurality of stents with the middle stents being considered as inner stents and a tubular graft body **2** surrounding the stents. It can also be seen there is a curved longitudinal support member **8** connected to the graft independent of the stents and has rounded ends **9,10**. Van Schie also discloses the longitudinal member can even be shorter or extend less than the distance between the end stents, paragraph 47. Van Schie et al. disclose the support member is a polymer or metal and is pre-formed in a curved shape, paragraph 45. The support member is substantially symmetrical with respect to a centerline that is about the middle of the device going around the circumference. It can be construed that the rounded ends are curved extremities and "substantially asymptotic". Regarding claims 91,96, Fig. 5 shows the stents have a linear profile. With respect to claims 92,97, it can be seen (Fig. 4) that the stents have a circular cross-sectional shape.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

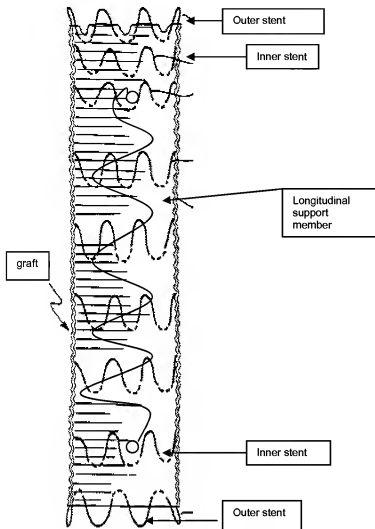
Claims 5,12,13,16,17,42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Philips et al. (WO 99/37242) in view of Bolea et al. (6821291). Philips is explained supra. However, Philips fails to disclose the longitudinal member has looped ends at the extremities. Bolea et al. teach (Fig. 22) a stent with a wire member having looped extremities **184**. Bolea et al. also teach that the loops enable an end to be collapsed to remove the stent device, col. 10, lines 31-36. It would have been obvious to one of ordinary skill in the art to use looped ends on a longitudinal wire support member as taught by Bolea et al. and incorporate into the stent graft of Philips et al. to provide the ability to remove the prosthesis if necessary.

Claims 16,17,51,75-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Schie et al. (2003/88305) in view of Bolea et al. (6821291). Van Schie et al. is explained supra. However, Van Schie et al. fail to disclose the support member extremity is curved back on itself. Bolea et al. teach (Fig. 18) that wire support members are curved back on themselves to form loops **170** to retrieve the stent at a later time, see entire patent for reason of loops. It would have been obvious to one of ordinary skill in the art to modify the extremities of the longitudinal support member as taught by Bolea et al. in the stent graft of Van Schie et al. such that the ability to retrieve the stent graft can be accomplished easily if the need arises in the patient.

Claims 18,19,20,21,24,25-29,53,55,57,59,80-82,85-87,90-92,95-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. (6099558) in view of Jayaraman (6464719). White et al. disclose a stent graft (Fig. 3) with a plurality of stents **17** and a tubular graft body **16**. It can also be seen (Fig. 2) that the stent graft has a distal and proximal stents **17a** that extend beyond the graft material and thus are outer stents. Regarding claims 53,55,57,59, White shows the graft body **10a,10b** has a diameter at least as large as a diameter of a normal vessel, **12,13** in which it is placed. However, White et al. fail to disclose a longitudinal support member. Jayaraman teaches (Fig. 8) a longitudinal support member 53 that is curved and shorter than the body of the stent graft and since it is joined to the graft, it is not touching the stents. Thus, by having the shorter length of the body of the stent graft it provides a gimbal. Jayaraman also teaches (Fig. 7) that the support members have looped ends **55**. Jayaraman additionally teaches that the longitudinal members have what can be construed as a partial helix shape or S-shapes joined together and used in expansion and made of nitinol, col. 2, lines 3,4,37,38. It is also noted that Jayaraman shows (Figs. 3,4) that the longitudinal curved members are connecting pieces for stent sections, col. 3, lines 29,30,53,54. It would have been obvious to one of ordinary skill in the art to use curved longitudinal support members as taught by Jayaraman in the stent graft of White et al. such that it provides more support to the vessel walls and assist in expansion and keep the stent in its expanded form together. Because Jayaraman's support member does not extend to the end of the graft, it can be said that it does not touch the

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first set of inner stents as illustrated below in the modified stent graft of White in view of Jayaraman's teaching.



Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Quinn '278 in view of Baker et al. (6346118). Quinn is explained supra. However, Quinn fails to disclose a distal most stent with an apex more than another of stents. Baker et al. teach (Fig. 21) a stent graft with a distal stent having an apex more than another of the stents. Baker et al. also teach that the farthest apex allows for better seals in a wall of a vessel, col. 12, lines 37-45. It

would have been obvious to one of ordinary skill in the art to use stents with a farther apex than other stents to better anchor in the vessel as taught by Baker et al. and incorporate into the stent graft of Quinn to improve the seal of the graft against the vessel wall.

Claims 48,50,54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Philips et al. (WO 99/37242) in view of Baker et al. (6346118). Philips is explained supra. However, Philips fails to disclose a distal most stent with an apex more than another of stents. Baker et al. teach (Fig. 21) a stent graft with a distal stent having an apex more than another of the stents. Baker et al. also teach that the farthest apex allows for better seals in a wall of a vessel, col. 12, lines 37-45. It would have been obvious to one of ordinary skill in the art to use stents with a farther apex than other stents to better anchor in the vessel as taught by Baker et al. and incorporate into the stent graft of Philips et al. to improve the seal of the graft against the vessel wall.

Claims 58,60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Schie et al. (2003/88305) in view of Baker et al. (6346118). Van Schie et al. is explained supra. However, Van Schie fails to disclose a distal most stent with an apex more than another of stents. Baker et al. teach (Fig. 21) a stent graft with a distal stent having an apex more than another of the stents. Baker et al. also teach that the farthest apex allows for better seals in a wall of a vessel, col. 12, lines 37-45. It would have been obvious to one of ordinary skill in the art to use stents with a farther apex than other stents to better anchor in the vessel

as taught by Baker et al. and incorporate into the stent graft of VanSchie et al. to improve the seal of the graft against the vessel wall.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Schie et al. (2003/88305) in view of Bolea et al. '291 as applied to claim 16 above, and further in view of Baker et al. '118. Van Schie et al. as modified by Bolea et al. is explained as before. However, Van Schie et al. in view of Bolea et al. fail to disclose a stent with an apex more than another of the stents. Baker et al. is explained supra. It would have been obvious to one of ordinary skill in the art to incorporate a farther apex on a distal stent as taught by Baker et al. with the stent graft of Van Schie et al. as modified by Bolea et al. such that it enhances the seal within the vessel wall.

Claims 54,56,58,60 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. '558 in view of Jayaraman '719 as applied to claims 18,20,25,28 above, and further in view of Baker et al. '118. White as modified by Jayaraman is explained as before. However, White in view of Jayaraman fail to disclose a stent with an apex more than another of the stents. Baker et al. is explained supra. It would have been obvious to one of ordinary skill in the art to incorporate a farther apex on a distal stent as taught by Baker et al. with the stent graft of White as modified by Jayaraman such that it enhances the seal within the vessel wall.

Claims 20,21,24,44,55,85-87 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al. (5723003) in view of Philips et al. (WO 99/37242). Winston et al. disclose a stent graft (Fig. 9) having a tubular graft

body **10** and a structural framework of first and second pairs of linear profile stents connected to the graft at proximal and distal ends and separated from one another to define outer **12** and inner **34** stents. Winston shows (Fig. 2) the stents have a circular cross-section. However, Winston et al. fail to disclose a longitudinal support member. Philips et al. is explained supra to teach a longitudinal support member. It would have been obvious to one of ordinary skill in the art to use the curved longitudinal support members as taught by Philips et al. in the stent graft of Winston et al. such that it provides more support to the stent graft and prevents kinking when the stent graft is bent in tortuous vessels.

Response to Arguments

Applicant's arguments filed 10/30/07 have been fully considered but they are not persuasive. Applicant failed to submit an argument regarding claims 25 and 28 pointing out disagreements with the examiner's contentions. The Examiner presented arguments in the Examiner's Answer that the VanSchie reference did apply to the claim language. In the response filed Applicant failed to discuss why VanSchie allegedly still does not read on the claims explaining how the claims avoid the references or distinguish from them. Thus, the rejections are maintained. Additionally, the Examiner is maintaining the rejections over independent claims 18,25,28 with respect to the obviousness rejection over White in view of Jayaraman since no arguments were provided to distinguish these claims against the references. The Examiner presented arguments in the Examiner Answer and the Applicant failed to proceed forward with them. Additionally, the rejections over White in view of Jayaraman are also maintained

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over the unamended claims in view of no arguments submitted to explain why the claims define over the prior art references. The Examiner presented arguments with respect to these rejections in the Examiner's Answer and no response regarding this was submitted. Applicant's amendments with respect to claims 1,15,16,20 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (9am-5:30pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700
/Brian E Pellegrino/
Primary Examiner, Art Unit 3738